EXHIBIT C

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE: NEW ENGLAND COMPOUNDING PHARMACY, INC. PRODUCTS LIABILITY LITIGATION	)	MDL No. 2419
	)	Dkt. No. 1:13-md-2419 (RWZ)
This Document Relates to:	)	
Suits Naming Specialty Surgery Center, Crossville, PLLC	)	

SPECIALTY SURGERY CENTER, CROSSVILLE, PLLC, AND KENNETH LISTER, MD'S RESPONSES TO THE PLAINTIFFS' STEERING COMMITTEE'S FIRST SET OF REQUESTS FOR ADMISSIONS AND CORRESPONDING INTERROGATORY

Pursuant to Rules 26, 33, and 36 of the Federal Rules of Civil Procedure and the Local Rules for the District of Massachusetts, Specialty Surgery Center, Crossville, PLLC ("SSC"), and Kenneth Lister, M.D. ("Dr. Lister"), provide the following responses to the Plaintiffs' Steering Committee's First Set of Requests for Admissions and Corresponding Interrogatory.

INTERROGATORY

1. If your response to any of the following Requests for Admission is anything other than an unqualified admission, for each such Request for Admission state all facts (not opinions) that you contend support in any manner your refusal to admit or your qualification of your admission, identify all documents, notes, reports, memoranda, electronic and/or tape recordings, photographs, oral statements, or any other tangible or intangible thing that supports in any manner your refusal to admit or your qualification of your admission, the name and address of the custodian of all tangible things identified above, and the name and address of all persons, including consultants and experts, purporting to have knowledge or factual data upon which you base your refusal to admit or the qualification of your admission.

RESPONSE:

Objection. This Interrogatory is overbroad, unduly burdensome, seeks the disclosure of expert opinions before the Court has set a schedule for such disclosures, seeks information that is irrelevant, not reasonably calculated to lead to the discovery of admissible evidence, and seeks information that is privileged from discovery by attorney-client privilege, the work-product doctrine, and the Tennessee Peer Review Law of 1967, Tenn. Code Ann. § 63-6-219 and/or the Tennessee Patient Safety and Quality Improvement Act of 2011, Tenn. Code Ann. §§ 63-1-150, 68-11-272.

Subject to and without waiving said objections, in response to this Interrogatory, these Defendants have incorporated into any denials or qualifications of these Requests for Admissions the basis or reason for the denial or qualification. Where the Response does not directly refer to non-privileged documents relied upon in making the denial or qualification, the Response provides a citation to the relevant supporting documentation.

REQUESTS FOR ADMISSIONS

1. Admit that in 2002, the CDC published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections. The report stated that "purchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that . . . follows appropriate measures to ensure that injectable products are free of contamination." A copy of that published report is attached as Exhibit 1.

RESPONSE:

These Defendants admit that the United States Centers for Disease Control ("CDC") published a report regarding at least two cases of fungal meningitis arising from contaminated medication used in epidural injections in 2002 and that the "Editorial Note" section states that "[p]urchasers of pharmaceuticals should determine if supplies are provided from a compounding pharmacy that is licensed in their state and that follows appropriate measures to ensure that injectable products are free of contamination." These Defendants deny that this is the entirety of the publication. These Defendants object, under Federal Rule of Evidence 106, to the admission of this limited excerpt from the CDC publication. These Defendants admit that Exhibit 1 appears to be a true and correct copy of the report referenced in Request for Admission #1.

2. Admit that Exhibit 1 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

3. Admit that Exhibit 1 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

4. Admit that Exhibit 1's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

5. Admit that, as to Exhibit 1, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. Roughly half of the authors are private and public university professors, physicians, and researchers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

6. Admit that on March 24, 2005, USA Today published a front page article with the following headline: **"Safety concerns grow over pharmacy-mixed drugs."** A true and correct copy of the text from that article is attached as Exhibit 2.

RESPONSE:

These Defendants admit that USA Today published an article titled "Safety concerns grow over pharmacy-mixed drugs." These Defendants insist that Federal Rule of Evidence 106 requires that the recipient of this Response also be informed that article also notes that (1) "regulators have long allowed [compounding] because 'the vast majority of pharmacies . . . provide a valuable medical service,'" (2) "proponents say compounding pharmacies overall are safe," (3) "several states are tightening their rules overseeing firms that compound drugs," and (4) "the FDA has stepped in when it decides a pharmacy has crossed the line and become a drug manufacturer." Based on information known or readily attainable, and after making reasonable inquiry, these Defendants lack sufficient information to admit or deny that the article was a front page story. These Defendants admit that Exhibit 2 appears to be a true and correct copy of the article referenced in Request for Admission #6.

7. Admit that in 2006, the FDA conducted a survey of compounded drug products. They collected thirty-six samples from compounding pharmacies across the United States during unannounced visits. Twelve of the 36 samples (33%) failed analytical testing. The FDA survey stated "poor quality compounded drugs are a serious public health concern, as improperly compounded products have been linked to grave adverse events, including deaths." A true and correct copy of the FDA's report titled *2006 Limited FDA Survey of Compounded Drug Products* is attached as Exhibit 3.

RESPONSE:

These Defendants admit that the FDA reported conducting a survey of compounded drug products in 2006. These Defendants admit that the study reported that the FDA collected 73 finished drug products from compounding pharmacies across the country during unannounced visits, but the FDA excluded 37 of the samples from the study because they were deemed unusable for various reasons. These Defendants admit that the study reported that, of the 36 samples tested, 12 (33%) failed analytic testing, but note under Federal Rule of Evidence 106, that "[m]ost of the products that failed analysis did so due to sub or super-potency . . . or a lack of uniformity of individual dosage units." These Defendants affirmatively state that the FDA did not test for sterility and that the study indicates that "[t]he majority of the finished compounded product samples analyzed in th[e] survey were hormone therapy products." The article also states that the "FDA has long recognized that traditional pharmacy compounding serves an important public health function." These Defendants admit that Exhibit 3 appears to be a true and correct copy of the report titled *2006 Limited FDA Survey of Compounded Drug Products*.

8. Admit that Exhibit 3 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

9. Admit that Exhibit 3 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock,* 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

10. Admit that Exhibit 3's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon, cite, or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

11. Admit that, as to Exhibit 3, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied in part. The article draws conclusions regarding sterility and contamination from articles in medical journals that were written by non-governmental employees. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees and is not a means to admit otherwise inadmissible hearsay medical journal articles. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993). References to issues with contamination and sterility are inferred and cited from inadmissible medical journal articles, which do not meet the public records exception of Federal Rule of Evidence 803(8). To the extent that the survey does not rely upon or draw conclusions from medical journal articles, it meets the hearsay exception codified at Federal Rule of Evidence 803(8).

12. In May 2007, the FDA published an article titled "The Special Risks of Pharmacy Compounding." A true and correct copy of that article is attached as Exhibit 4.

RESPONSE:

These Defendants admit that the FDA published an article titled "The Special Risks of Pharmacy Compounding" in May 2007. These Defendants admit that Exhibit 4 appears to be a true and correct copy of the report referenced in Request for Admission #12.

13. Admit that Exhibit 4 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

14. Admit that Exhibit 4 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman, 1*50 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler*, 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler*, 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan*, 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

15. Admit that Exhibit 4's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman, 1*50 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

16. Admit that, as to Exhibit 4, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not (1) drafted pursuant to a legally authorized investigation, (2) a final agency action, or (3) a binding document upon the FDA. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); 21 C.F.R. § 10.85(k) ("[a] statement or advice given by an FDA employee. . . is an informal communication that represents the best judgment of that employee at that time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

17. Admit that in 2010, the FDA posted an educational video on YouTube regarding compounded drugs. That educational video is found on the World Wide Web at http://www.youtube.com/watch?v=kif_rmtIQb0.

RESPONSE:

These Defendants admit that the FDA posted an educational video on YouTube in 2010 regarding concerns over the quality of compounded drugs.

18. Admit that on November 5, 2010, the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP") and other medical societies published a joint report regarding drug shortages. That report included an article written by the ASHP stating as follows:

> Compounding pharmacies have also pursued the production of drugs that are in short supply. Caution is warranted because preparations from these pharmacies may not meet applicable state or federal standards (*e.g.*, United States Pharmacopeia chapter 797 or FDA labeling requirements). The sources of raw materials used by compounding pharmacies have been questioned, and apparent lapses in quality control have resulted in serious patient injury, including death.
>
> . . .
>
> Compounding pharmacies may also present patient risks; several deaths have been associated with improperly sterilized compounded products.

An excerpt from that joint report is attached as Exhibit 5.

RESPONSE:

These Defendants admit that the American Society of Anesthesiologists, the American Society of Health-System Pharmacists ("ASHP"), and other medical societies published a joint report regarding drug shortages, and that the report included an article written by the ASHP with the quote included in Request for Admission #18. These Defendants deny this is the entire report or that it applies to them.

These Defendants admit that Exhibit 5 is a nine (9) page excerpt from the 52 page report. These Defendants object to introduction of excerpts from a nine (9) page document embedded in a 52 page report pursuant to Federal Rule of Evidence 106. These Defendants deny that the report was published on November 5, 2010. The report was created for a Drug Shortages Summit that occurred on November 5, 2010, but the report was not published until on or about January 10, 2011.[1]

[1] http://www.asahq.org/For-Members/Advocacy/Washington-Alerts/Drug-Shortages-Summit-Summary-Released.aspx.

19. Admit that on [sic] May 2012, the CDC published a report regarding fungal infections arising from medications obtained from a compounding pharmacy. That report advised that "contamination of compounded sterile preparations has caused outbreaks. Since 1990, FDA has learned of approximately 200 adverse events associated with 71 compounded products." Portions of that report are attached as Exhibit 6.

RESPONSE:

These Defendants admit that the CDC published a report in May 2012 regarding fungal infections arising from medications obtained from a compounding pharmacy and that the report states that "contamination of compounded sterile preparations has caused outbreaks." The article noted that, in 22 years, the "FDA has learned of approximately 200 adverse events associated with 71 compounded products." The report further states that "[c]ompounded sterile preparations must be prepared according to aseptic practices recommended by organizations such as the United States Pharmacopeia, as stated in United States Pharmacopeia-National Formulary (3)" These Defendants affirmatively state that NECC represented that it complied with the relevant standards of the United States Pharmacopeia. These Defendants admit that Exhibit 6 appears to be a true and correct copy of the report referenced in Request for Admission #19. These Defendants deny that this is the entirety of the publication. These Defendants object, under Federal Rule of Evidence 106, to the admission of this limited excerpt from the CDC publication.

20. Admit that Exhibit 6 is "a record or statement of a public office" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental health care providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

21. Admit that Exhibit 6 sets out "factual findings from a legally authorized investigation" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental health care providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman, 150* F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

22. Admit that Exhibit 6's source of information does not "indicate a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental health care providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman,* 150 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

23. Admit that, as to Exhibit 6, no other circumstance "indicate[s] a lack of trustworthiness" as that term is used in Federal Rule of Evidence 803(8).

RESPONSE:

Denied. The article is not written by governmental employees. At least three of the authors are non-governmental health care providers. The presumption of trustworthiness, which is the basis for the public records exception to the hearsay rule, does not apply to documents created wholly or in part by non-governmental employees, and Rule 803(8) is not a means to admit otherwise inadmissible hearsay statements of non-governmental employees. *See Toole v. McClintock*, 999 F.2d 1430, 1435 (11th Cir. 1993).

Additionally, the article is not (1) a final agency action or (2) a binding document upon the CDC. *Genendo Pharmaceutical NV v. Thompson*, 308 F. Supp. 2d 881 (N.D. Ill. 2003) ("Statements of lower-level agency officials likewise do not rise to the level of final agency action-even when they are contained in warning letters or other official regulatory correspondence."); *Schering-Plough Healthcare v. Schwarz Pharma*, 547 F. Supp. 2d 939 (E.D. Wis. 2008); *see, e.g., Western Ill. Home Health Care v. Herman, 1*50 F.3d 659, 662 (7th Cir. 1998); *Schering Corp. v. Heckler,* 779 F.2d 683, 686 n. 18 (D.C. Cir. 1985); *Biotics Research Corp. v. Heckler,* 710 F.2d 1375, 1378 (9th Cir. 1983); *Clinical Reference Laboratory, Inc. v. Sullivan,* 791 F. Supp. 1499, 1503-04 (D. Kan. 1992).

24. Admit that in 2010, the American Society of Health System Pharmacists published the "ASHP Guidelines on Outsourcing Sterile Compounding Services." A true and correct copy of that publication is attached as Exhibit 7.

RESPONSE:

These Defendants admit that Exhibit 7 appears to be a true and correct copy of the guidelines referenced in Request to Admit #24 but deny that the guidelines apply to them. The guidelines were developed to assist health care organizations in deciding whether to outsource sterile pharmacy compounding performed within a hospital.

25. Admit that the American Society of Health System Pharmacists developed a "Contractor Assessment Tool" for health care organizations to use in conjunction with assessing compounding pharmacies. A true and correct copy of that assessment tool is attached as Exhibit 8.

RESPONSE:

Denied. The "Outsourcing Sterile Products Preparation: Contractor Assessment Tool" was developed by the ASHP Foundation and PharMEDium Services, LLC for health-system pharmacy departments that choose to outsource the preparation of sterile parenteral medications.[2] Based on information known or readily attainable, and after making reasonable inquiry, these Defendants lack sufficient information to admit or deny that the "Contractor Assessment Tool" was developed for use "in conjunction with assessing compounding pharmacies." These Defendants admit that Exhibit 8 appears to be a true and correct copy of the document referenced in Request for Admission # 25 but deny that it applies to them.

26. Admit that in December 2011, the International Academy of Compounding Pharmacists published the "Compounding Pharmacy Assessment Questionnaire." A true and correct copy of that questionnaire is attached as Exhibit 9.

RESPONSE:

Denied as stated. The IACP published the "Compounding Pharmacy Assessment Questionnaire" in October 2011, not December.[3] Additionally, these Defendants affirmatively state that the questionnaire is designed to obtain a representation by the compounder of compliance with United States Pharmacopeia (USP) standards with which NECC represented that it complied.[4] These Defendants admit that Exhibit 9 appears to be a true and correct copy of the questionnaire referenced in Request for Admission # 26.

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[2] http://www.ashpfoundation.org/sterileproductstool

[3] http://www.iacprx.org/associations/13421/files/IACP%20Press%20Release%20CPAQ%20Tool%20Announcement%2010052011.pdf

[4] *Id.*

27. Admit that NECC operated a compounding pharmacy in Framingham, Massachusetts on a site shared with a mattress recycling and/or garbage compacting operation.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that NECC operated a compounding pharmacy in Framingham, Massachusetts on a site shared with a mattress recycling and/or garbage compacting operation.

28. Admit that NECC compounded MPA in so-called "clean rooms" that were filthy.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that NECC compounded methylprednisolone acetate ("MPA") in cleanrooms that were "filthy."

29. Admit that a leaky boiler stood in a pool of stagnant, dirty water at NECC's compounding facility.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that a leaky boiler stood in a pool of stagnant, dirty water at NECC's compounding facility.

30. Admit that the autoclaves used to sterilize products at NECC were discolored, tarnished, and contained visible moisture.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that the autoclaves used to sterilize products at NECC were discolored, tarnished, and contained visible moisture.

31. Admit that the air vents in the NECC "clean" rooms were covered with dirt and white fuzz.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that the air vents in the NECC "clean" rooms were covered with dirt and white fuzz.

32. Admit that the metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

RESPONSE:

These Defendants admit that, after various government agencies began their investigation of NECC after the fungal meningitis outbreak, it was reported that the metal shelf in the "clean" room used to prepare MPA was covered in a reddish-brown, cloudy substance.

33. Admit that Specialty Surgery is a for-profit professional limited liability company.

RESPONSE:

Admitted.

34. Admit that Specialty Surgery administers epidural steroid injections to patients for profit.

RESPONSE:

Denied as stated. Dr. Lister administered epidural steroid injections at SSC as a health care service provided for the intended benefit of patients. These Defendants admit that SSC was a for-profit limited liability company. SSC dissolved in 2014.

35. Admit that Dr. Lister was the Medical Director for Specialty Surgery in 2012.

RESPONSE:

Denied.

36. Admit that Dr. Lister was an agent, employee or member of Specialty Surgery throughout 2012.

RESPONSE:

These Defendants admit that Dr. Lister was a member of SSC in 2012.

37. Admit that Debra Schamberg, R.N. was the Facilities Director for Specialty Surgery in 2012.

RESPONSE:

Denied.

38. Admit that Debra Schamberg, R.N was an agent, employee or member of Howell Allen Clinic throughout 2012.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Neither Debra Schamberg, R.N. nor the Howell Allen Clinic is in any way related to SSC.

39. Admit that Specialty Surgery's Facility Director, Debra Schamberg, R.N., is an employee of Howell Allen Clinic.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Neither Debra Schamberg, R.N. nor the Howell Allen Clinic is in any way related to SSC. Subject to and without waiving said objections, this Request for Admission is denied.

40. Admit that Specialty Surgery's Medical Director, John Lister, M.D. is an employee of Howell Allen Clinic.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Neither John Lister, M.D. nor the Howell Allen Clinic is in any way related to SSC. Subject to and without waiving said objections, this Request for Admission is denied.

41. Admit that all persons working at Specialty Surgery in 2012 were employees of Howell Allen Clinic.

RESPONSE:

Denied.

42. Admit that Debra Schamberg R.N. and John Lister, M.D. used Howell Allen Clinic email addresses in 2012.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. John Lister, M.D., Debra Schamberg, R.N. and the Howell Allen Clinic are not in any way related to SSC.

43. Admit that all persons working at Specialty Surgery used Howell Allen Clinic email addresses in 2012.

RESPONSE:

Denied.

44. Admit that Specialty Surgery's Facility Director, Debra Schamberg, is part of Howell Allen Clinic's Staff.

RESPONSE:

Objection. This Request for Admission seeks information that is irrelevant and not reasonably calculated to lead to the discovery of admissible evidence. Neither Debra Schamberg, R.N. nor the Howell Allen Clinic is in any way related to SSC.

45. Admit that Scott Butler is the Chief Administrative Officer and/or CEO of Howell Allen Clinic.

RESPONSE:

Objection. These Defendants object to this request for admission on the grounds that it is not reasonably calculated to lead to the discovery of admissible evidence. Neither Scott Butler nor the Howell Allen Clinic is in any way related to SSC.

46. Admit that Scott Butler reported to the *Tennessean* that Specialty Surgery started 12 years ago as a joint venture between Saint Thomas Network and Howell Allen Clinic.

RESPONSE:

Denied.

47. Admit that Scott Butler reported to the *Tennessean* that Howell Allen Clinic manages the hiring and workers at Specialty Surgery.

RESPONSE:

Denied.

48. Admit that Scott Butler reported to the *Tennessean* that Saint Thomas Network handles contracting, credentialing and finances at Specialty Surgery.

RESPONSE:

Denied.

49. Admit that Dr. Lister managed Specialty Surgery's day-to-day operations.

RESPONSE:

Denied.

50. Admit that Dr. Lister was directly involved with and responsible for Specialty Surgery's decision to purchase MPA from NECC.

RESPONSE:

These Defendants admit that Dr. Lister participated in and had responsibility for the decision to purchase MPA from NECC.

51. Admit that Specialty Surgery, and/or Dr. Lister made the decision to purchase MPA in bulk from NECC because it was the cheapest alternative.

RESPONSE:

Denied.

52. Admit that Specialty Surgery did not use patient-specific individual prescriptions when buying MPA from NECC in bulk.

RESPONSE:

These Defendants admit that they provided patient names, not individual prescription slips, when ordering from NECC but deny that the standard of acceptable professional practice required them to.

53. Admit that Specialty Surgery could have purchased Depo-medrol (or the generic version of that drug) manufactured by an FDA regulated pharmaceutical manufacturer such as Pfizer or Teva for use in epidural steroid injections.

RESPONSE:

Objection. This Request for Admission is overbroad and seeks information that is not reasonably calculated to lead to the discovery of admissible evidence as it does not identify a time period during which SSC allegedly could have purchased MPA from "an FDA-regulated pharmaceutical manufacturer such as Pfizer or Teva for use in epidural steroid injections." These Defendants admit that SSC could have purchased MPA from Pfizer and/or Teva for use in epidural steroid injections at some point in time. Additionally, these Defendants affirmatively state that NECC was regulated by the FDA. Beyond that, these Defendants cannot further respond.

54. Admit that Specialty Surgery purchased 220 vials of MPA from NECC during the time period July through August 2012.

RESPONSE:

Admitted.

55. Admit that the Tennessee Department of Health and the United States Centers for Disease Control and Prevention ("CDC") began investigating a fungal meningitis outbreak in September 2012.

RESPONSE:

These Defendants admit that the Tennessee Department of Health and the CDC began investigating a cluster of meningitis cases in September 2012. These Defendants deny that the volume of cases in September 2012 rose to the level of an "outbreak" or that a definitive determination had been reached that the disease state was fungal meningitis in September 2012.

56. Admit that several patients of Specialty Surgery were diagnosed with fungal meningitis after being injected with MPA procured from NECC.

RESPONSE:

Admitted.

57. Admit that attached as Exhibit 10 is a true and correct copy of information from the CDC website located at http://www.cdc.gov/hai/outbreaks/meningitis-facilities-map.html.

RESPONSE:

Admitted.

58. Admit that according to the CDC, NECC recalled the following lots of methylprednisolone acetate (PF) 80mg/ml on September 26, 2012:

- Lot #05212012@68, BUD 11/17/2012;
- Lot #06292012@26, BUD 12/26/2012; and
- Lot #08102012@51, BUD 2/6/2013.

RESPONSE:

Admitted.

59. Admit that according to the CDC, Specialty Surgery received MPA from NECC that was from one or more of the recalled lots.

RESPONSE:

Admitted.

60. Admit that attached as Exhibit 11 is a true and correct copy of the FDA Form 483 for New England Compounding Center issued on October 26, 2012.

RESPONSE:

Admitted.

61. Admit that the FDA analyzed 50 vials from lot 08102012@51 (one of the three lots originally recalled by NECC).

RESPONSE:

These Defendants admit that Exhibit 11 states that the FDA analyzed 50 vials of FDA Sample #693965, consisting of methylprednisolone acetate (PF) 80mg/mL, 1mL filled vials, from lot 08102012@51 collected from NECC.

62. Admit that the FDA confirmed the presence of viable microbial growth in 50 out of 50 vials tested from lot 08102012@51.

RESPONSE:

These Defendants admit that Exhibit 11 states that the FDA analyzed 50 vials of FDA Sample #693965, consisting of methylprednisolone acetate (PF) 80mg/mL, 1mL filled vials, from lot 08102012@51 collected from NECC and confirmed the presence of viable microbial growth in all 50 of the vials tested.

63. Admit that attached as Exhibit 12 is a true and correct copy of CDC laboratory confirmed results from three NECC MPA lots recalled on September 26, 2012.

RESPONSE:

These Defendants admit that Exhibit 12 is a true and correct copy of CDC laboratory confirmed results from three of NECC's methylprednisolone acetate (PF) lots recalled on September 26, 2012 as summarized and reported on the CDC website. These Defendants deny that Exhibit 12 contains the actual laboratory data.

64. Admit that the CDC isolated *Exserohilum rostratum* in two of the three lots of MPA originally recalled from NECC.

RESPONSE:

These Defendants admit that Exhibit 12 states that tests at the CDC and FDA had confirmed the presence of *Exserohilum rostratum* in unopened vials from two of the three recalled lots.

65. Admit that according to the CDC, *Exserohilum rostratum* is the same fungus as the one found in laboratory-confirmed cases of human infection.

RESPONSE:

Denied as stated. The CDC reported identifying twelve (12) different fungi in case patients, in addition to *Exserohilum rostratum*. These Defendants admit that the CDC reported that *Exserohilum rostratum* was the "predominant fungal infection in this outbreak."

66. Admit that epidural steroid injections administered to various patients at Specialty Surgery were contaminated with fungus.

RESPONSE:

These Defendants have made a reasonable inquiry and the information known and readily obtainable is insufficient to permit an admission or denial. It is admitted that patients had fungal meningitis after injections. However, all but one of the empty vials of MPA used during patients' procedures were destroyed following their procedures in accordance with generally-accepted practices for disposing of medical waste.

67. Admit that epidural steroid injections administered to various patients at Specialty Surgery caused them to contract fungal meningitis. That disease caused some patients to die, and it sickened others.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, this Request for Admission is denied as stated. Contaminated medication received by SSC from NECC caused patients to contract fungal meningitis, not the health care services provided by physicians at SSC. These Defendants admit that the disease caused some patients to die and sickened others.

68. Admit that fungal meningitis caused some Specialty Surgery patients to die.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, these Defendants admit, based upon information, belief and reasonable inquiry, that fungal meningitis caused some SSC patients to die.

69. Admit that fungal meningitis sickened some Specialty Surgery patients.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, these Defendants admit, based upon information, belief, and reasonable inquiry, that fungal meningitis sickened some SSC patients.

70. Admit that no facts suggest that patients who contracted fungal meningitis after receiving epidural steroid injections at Specialty Surgery administered during July, August and/or September of 2012 contracted that disease from any source other than those epidural steroid injections.

RESPONSE:

Objection. This Request for Admission seeks an expert opinion and/or medical causation testimony before the Court has set a deadline for disclosing experts.

Subject to and without waiving said objection, these Defendants admit, upon information and belief, that patients who contracted fungal meningitis after receiving epidural steroid injections at SSC administered during July, August, and/or September of 2012 contracted the fungal meningitis as a result of receiving contaminated medication from NECC during their treatment at SSC. However, at this point, full investigation of the pathology of each individual infection has not been completed.

Respectfully submitted,

GIDEON, COOPER & ESSARY, PLC

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* Admitted pursuant to MDL Order No. 1.
** Admitted *pro hac vice*.

CERTIFICATE OF SERVICE

I hereby certify that on the 27th day of October, 2014, a true and accurate copy of the foregoing was served on the PSC by hand-delivery and on the other parties below by serving a notice indicating that the PSC will upload the responses to the discovery repository in the MDL:

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